DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2015

Dallen Medical, Incorporated
Mr. Al Memmolo
Chief Operating Officer
1046 Calle Recodo, Suite G
San Clemente, California 92673

Re: K150359
Trade/Device Name: Tensyn™ Plug
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: February 11, 2015
Received: February 12, 2015

Dear Mr. Memmolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K150359

Device Name: **Tensyn™ Plug**

Indications for Use:

The subject device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Tensyn Plug is intended to provide fixation during the healing process following:

- A syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures
- Acromioclavicular separations due to coracoclavicular ligament disruptions
- Syndesmotic trauma, such as fixation of dorsal distal radiolunar ligament (DRUL) disruptions;
- Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
- Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal -2nd metatarsal intermetatarsal angle.

The Tensyn Plug, when used for fixation of bone-to-bone or soft-tissue to- bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Tensyn Plug is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Prescription Use __X__ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

GENERAL INFORMATION

APPLICANT: Dallen Medical, Inc.
1046 Calle Recodo, Suite G
San Clemente, CA 92673
(949) 218-0030 Phone
(949) 218-0040 Fax

CONTACT PERSON: Al Memmolo
Chief Operating Officer

DATE PREPARED: April 10, 2015

DEVICE DESCRIPTION:

TRADE NAME: Tensyn™ Plug

GENERIC/COMMONNAME Button / Lock / Suture

CLASSIFICATION NAME: Washer, Bolt Nut, CFR 888.3030 (code HTN)

DEVICE CLASSIFICATION: Class II

PREDICATE DEVICES: Tensyn Plug (K143092)
TightRope Syndesmosis Device (K043248)

Product Description:

The Tensyn Plug is a knotless system for fixation of syndesmosis disruptions, acromioclavicular repair, tarasometatarsal injury, hallux valgus reconstruction, and carpal metacarpal joint arthroplasty. The Tensyn Plug is a low profile system comprised of a coated flat polyethylene terephthalate (PET) suture band tensioned and secured between a narrow button and a locking cap assembly. The Tensyn Plug is available in stainless steel and titanium.

Indications for Use:

The subject device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Tensyn Plug is intended to provide fixation during the healing process following:

- A syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures
- Acromioclavicular separations due to coracoclavicular ligament disruptions
- Syndesmotic trauma, such as fixation of dorsal distal radiolunar ligament (DRUL) disruptions;
- Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
- Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal -2nd metatarsal intermetatarsal angle.

The Tensyn Plug, when used for fixation of bone-to-bone or soft-tissue to- bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Tensyn Plug is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Technical Characteristics:

The Tensyn Plug has similar physical and technical characteristics to the predicate devices since all devices achieve fixation through a suture between two metal fasteners.

Performance Data:

All necessary testing has been performed with the Tensyn Plug to assure substantial equivalence to the predicate devices. Testing included rotational loading, cyclic loading, ultimate load, load at 3 mm and shear test. The testing demonstrated that the Tensyn Plug is substantially equivalent to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the technical information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Tensyn Plug is determined to be substantially equivalent to existing legally marketed devices.